

Pending Legislation Related to Human Subject Research November 2007

The following is garnered from the Library of Congress and includes the current status on bills pending in the House & Senate. This is NOT a comprehensive list (e.g. none of the several dozen or so current bills on stem cell research are included). It is merely intended as a heads up on legislation introduced that you may not be aware of.

Sessions of Congress last two years, and at the end of each session all proposed bills and resolutions that haven't passed are cleared from the books, hence the phrase "died in committee."

S.2358, Human-Animal Hybrid Prohibition Act of 2007 (introduced 11/15/2007)

Sponsor: Sen Brownback, Sam [KS] Cosponsors (18)

Latest Major Action: 11/15/2007 Referred to Senate Committee on the Judiciary.

A bill to amend title 18, US Code, to prohibit human-animal hybrids.

(a) In General- It shall be unlawful for any person to knowingly, in or otherwise affecting interstate commerce--

- (1) create or attempt to create a human-animal hybrid;
- (2) transfer or attempt to transfer a human embryo into a non-human womb;
- (3) transfer or attempt to transfer a non-human embryo into a human womb; or
- (4) transport or receive for any purpose a human-animal hybrid.

Whoever violates subsection (a) shall be fined under this title, imprisoned not more than 10 years, or both.

Whoever violates subsection (a) and derives pecuniary gain from such violation shall be subject to a civil fine of the greater of \$1,000,000 and an amount equal to the gross gain multiplied by 2.

S.1814, Health Information Privacy and Security Act (introduced 7/18/2007)

Sponsor: Sen Leahy, Patrick J. [VT] Cosponsors (2)

Latest Major Action: 7/18/2007 Referred to Senate Committee on Health, Education, Labor, and Pensions.

A bill to provide individuals with access to health information of which they are a subject, ensure personal privacy with respect to health related information, promote the use of non-identifiable information for health research, impose criminal and civil penalties for unauthorized use of protected health information, to provide for the strong enforcement of these rights, and to protect States' rights. Under this bill, misuse of information could result in criminal penalties up to \$500,000 and 10 years in prison in addition to civil penalties.

H.R.268, Energy Employees Occupational Illness Compensation Program Improvement Act of 2007
Sponsor: Rep Jackson-Lee, Sheila [TX-18] (introduced 1/5/2007) Cosponsors (None)
Latest Major Action: 5/9/2007 Referred to House Subcommittee on Workforce Protections.

Amends the EEOICP Act of 2000 to clarify the roles and responsibilities of the agencies and actors responsible for the administration of such compensation program.

Instructs the Secretary of Energy to designate annually as a beryllium vendor any vendor, processor, or producer of beryllium (or related products) not previously designated as such if the Secretary finds that such person has engaged in activities related to production or processing of beryllium sales.

Transfers certain responsibilities from the President to the Secretary of HHS regarding: (1) Program administration; and (2) the Special Exposure Cohort.

Revises requirements for: (1) the Advisory Board on Radiation and Worker Health (Board); and (2) the Special Exposure Cohort.

S.1070, Elder Justice Act (introduced 3/29/2007)
Sponsor: Sen Hatch, Orrin G. [UT] Cosponsors (18)
Latest Major Action: 3/29/2007 Referred to Senate Committee on Finance.

Establishes within the Office of the Secretary of Health and Human Services (HHS) an Elder Justice Coordinating Council (EJCC) and calls for increased protections when conducting research on the aged.

House version

H.R.1783 Elder Justice Act (introduced 3/29/2007)
Sponsor: Rep Emanuel, Rahm [IL-5] Cosponsors (86)
Latest Major Action: 6/27/2007 Referred to House Subcommittee on Healthy Families and Communities.

Similar to S1070

H.R.788 Food and Drug Administration Safety Act of 2007 (introduced 1/31/2007)
Sponsor: Rep Tierney, John F. [MA-6] Cosponsors (5)
Latest Major Action: 2/2/2007 Referred to House subcommittee on Health.

To amend the FDA Act to provide better protection for human research subjects and the general public with respect to drug safety.

There is also a Senate version of this bill (S468), and it too was referred to committee.

H.R.5578 Protection for Participants in Research Act of 2006 (introduced 6/9/2006)

Sponsor: Rep DeGette, Diana [CO-1] Cosponsors (5)

Latest Major Action: Referred to House subcommittee on Health 6/23/2006.

This is the 3rd time DeGette has submitted this bill (see HR3594 [2003] and HR4697 [2002]). All previous attempts died in committee, and this one appears stuck there as well.

Amends the Public Health Service Act to reiterate a lot of standard language we all know by heart regarding IRBs and informed consent, but also contains some new notions:

- Directs the Secretary to establish criteria for identifying and monitoring high-risk HS research projects. [03, 02]
- Requires the Secretary to promulgate regulations enhancing the protection of people with diminished decisionmaking capacity participating in HS research. [03, 02] *This clause now appears in several other unrelated bills this year.*
- Prohibits the use of federal funds for classified research if: (1) the IRB has waived the informed consent requirement; or (2) the research is exempt from IRB review. [03, 02]

This latter contingency is curious, because some legal experts contend that current law precludes exemption for classified research.
